February 23, 2020

Stryker Trauma GmbH
Sanja Jahr
Senior Regulatory Affairs Specialist, Trauma and Extremities
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K193308
Trade/Device Name: T2 Alpha Tibia Nailing System, IMN Screws System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Codes: HSB, HWC
Dated: November 27, 2019
Received: November 29, 2019

Dear Sanja Jahr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Michael Owens
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193308

Device Name
T2 Alpha Tibia Nailing System

Indications for Use *(Describe)*

The indications for use of this internal fixation device include:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Fractures involving osteopenic and osteoporotic bone
- Nonunion and malunion

The End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF may also be used in conjunction with the T2 Alpha Femur Antegrade GT/PF Nailing System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193308

Device Name
IMN Screws System

Indications for Use *(Describe)*
The IMN Screws System is intended to stabilize the intramedullary nail-bone construct for temporary stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. SUBMITTER

Sponsor: Stryker Trauma GmbH
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Mahwah, NJ 07430
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Date Prepared: November 27, 2019

II. DEVICE

Name of Device: T2 Alpha Tibia Nailing System
IMN Screws System

Common Name: T2 Alpha Tibia Nailing System
Rod, fixation, intramedullary and accessories
IMN Screws System
Screw, fixation, bone

Regulation Number / Name: T2 Alpha Tibia Nailing System
21CFR 888.3020 (Intramedullary fixation rod)
IMN Screws System
21CFR 888.3040 (Smooth or threaded metallic bone fixation fastener)

Product Code: T2 Alpha Tibia Nailing System
HSB (Rod, fixation, intramedullary and accessories)
IMN Screws System

HWC (Screw, fixation, bone)

Regulatory Class: Class II

III. PREDICATE DEVICE

T2 Alpha Tibia Nailing System

Predicate device: T2 Alpha Tibia Nailing System (K191271)

Reference device: Titan Tibial Nail (K003018)

IMN Screws System

Predicate device: IMN Screws System (K191271)

Reference device: Titan Tibial Nail (K003018)

Synthes Tibial Nail System Ex (K040762)

IV. DEVICE DESCRIPTION

A Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market for:

- Line extension to T2 Alpha Tibia Nailing System (addition of Ø8 mm nails)
- Line extension to IMN Screws System (addition of Ø4 mm locking screws and Ø4 mm advanced locking screws)

The T2 Alpha Tibia Nailing System and IMN Screws System were most recently cleared in K191271, and the intended use and indications for use remain unchanged. The T2 Alpha Tibia Nailing System and IMN Screws System have a similar intended use and are used together during a surgical procedure.

T2 Alpha Tibia Nailing System

The T2 Alpha Tibia Nailing System, previously cleared in K191271, is a fracture fixation system and includes sterile implants (tibial nails in various diameters, compression screw tibia and end caps) as well as non-sterile instruments (targeting devices).

The sterile implants (Tibial Nail, Compression Screw Tibia, End Cap Tibia, and End Cap Lower Extremity) are made of titanium alloy (Ti6Al4V ELI) per ASTM F136. The adapters and nail holding screws are manufactured from stainless steel. The Targeting Arm Tibia and Adjusting Device Tibia are made of stainless steel, PEEK unreinforced as well as PEEK with 30% and 50% carbon fibers. The Distal Targeting Arm Tibia is made of PEEK with 30% and 50% carbon fibers.

The distal end of the Ø8 mm tibial nail is compatible with the new Ø4 mm Locking Screw and Ø4 mm Advanced Locking Screw of the IMN Screws System. However, the proximal end of the Ø8 mm tibial nail is compatible with the existing Ø5 mm Locking Screw and Ø5 mm Advanced Locking Screw of the IMN Screws System. The already cleared Ø9-15 mm T2 Alpha Tibial Nail can be used with the Ø5 mm locking screws from the Titan Tibial Nail (K003018), or the Ø5 mm locking screws and advanced locking screws from the IMN Screws System (K191271). The T2 Alpha Tibia Nailing System is intended to be used with the surgical instruments of the T2 Tibial Nailing System (K131365) as well as the surgical instruments from the IMN Instruments System and T2 Instruments System (510(k) exempt devices). Furthermore, the End Cap Lower Extremity and the Nail Holding Screw Tibia/Femur PF of T2 Alpha Tibia Nailing System can be used with the T2 Alpha Femur Antegrade GT/PF Nailing System (K191271).

IMN Screws System

The IMN Screws System, most recently cleared in K191271, includes bone screws (locking screws and advanced locking screws) that are inserted through the intramedullary nail to stabilize the nail-bone construct. The new Ø4 mm locking screws and advanced locking screws can only be used at the distal end of the new Ø8 mm tibial nails. All screws are made of titanium alloy (Ti6Al4V ELI) per ASTM F136. The IMN Screws System is intended for use with the T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Alpha Tibia Nailing System and IMN Instruments System.

V. INTENDED USE

T2 Alpha Tibia Nailing System

The T2 Alpha Tibia Nailing System is intended for temporary stabilization of bone segments or fragments until bone consolidation has been achieved.

IMN Screws System

The IMN Screws System is intended to stabilize the intramedullary nail-bone construct for temporary stabilization.

VI. INDICATION FOR USE

T2 Alpha Tibia Nailing System

The indications for use of this internal fixation device include:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Fractures involving osteopenic and osteoporotic bone

- Nonunion and malunion

The End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF may also be used in conjunction with the T2 Alpha Femur Antegrade GT/PF Nailing System.

IMN Screws System

The IMN Screws System is intended to stabilize the intramedullary nail-bone construct for temporary stabilization.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

T2 Alpha Tibia Nailing System

Device comparison demonstrated that the new Ø8 mm tibia nail, of the T2 Alpha Tibia Nailing System, is substantially equivalent to the existing nails of the T2 Alpha Tibia Nailing System (K191271), and to the Titan Tibial Nail (K003018). The subject device and the predicate devices have the same intended use, indications for use, technological characteristics (design features, material and performance) as well as operating principle. At a high level, the subject device and predicate devices have the same technological characteristics, which include:

- Intramedullary nailing systems to provide a fracture fixation of the tibia,
- Nail and screw design (length, diameter, and shape), and
- Nails, compression screw and end caps manufactured from titanium alloy (Ti6Al4V ELI) per ASTM F136.
- Hole configurations in proximal and distal part of nail, and
- Locking configurations.

IMN Screws System

Device comparison demonstrated that the new Ø4 mm locking screw and Ø4 mm advanced locking screw, of IMN Screws System, are substantially equivalent to the existing screw of the IMN Screws System (K191271), and to the screws of the Titan Tibial Nail (K003018), as well as the screws of the Synthes Tibial Nail System Ex (K040762). The subject devices and the predicate devices have the same intended use, indications for use, technological characteristics (design features, material and performance) as well as operating principle. At a high level, the subject device and predicate devices are based on the same technological characteristics, which include:

- Stabilization of intramedullary nail-bone construct,
- Used for proximal and distal locking of nail-bone construct,
- Design (length, diameter, thread design), and

- Manufactured from titanium alloy (Ti6Al4V ELI) per ASTM F136.

VIII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

T2 Alpha Tibia Nailing System

Comparative mechanical testing to the predicate systems demonstrated substantial equivalence. The following tests were performed:

- Testing of mechanical properties per ASTM F1264
- Fatigue strength testing (distal)

Mechanical testing and performance assessments demonstrate that the new Ø8 mm tibial nail, of the T2 Alpha Tibia Nailing System, is equivalent to the predicate devices (K191271, K003018).

MR assessments of magnetically-induced displacement force, magnetically-induced torque, RF-induced heating, and image artifacts demonstrate that the T2 Alpha Tibia Nailing System is MR conditional.

The Bacterial Endotoxin Testing demonstrated that the sterile implants of T2 Alpha Tibia Nailing System meet the specified endotoxin limit.

IMN Screws System

Comparative mechanical testing to the predicate systems demonstrated substantial equivalence. The following tests were performed:

- Testing of mechanical properties as per ASTM F543 and F1264.

Mechanical testing demonstrated that the new Ø4 mm locking screw and Ø4 mm advanced locking screws, of the IMN Screws System, are equivalent to the predicate devices (K191271) and reference device (K003018, K040762).

MR assessments of magnetically-induced displacement force, magnetically-induced torque, RF-induced heating, and image artifacts demonstrate that the IMN Screws System is MR conditional.

The Bacterial Endotoxin Testing demonstrated that the advanced locking screws meet the specified endotoxin limit.

IX. CLINICAL TESTING

T2 Alpha Tibia Nailing System

No clinical testing of the T2 Alpha Tibia Nailing System has been conducted.

IMN Screws System

No clinical testing of the IMN Screws System has been conducted.

X. CONCLUSION

T2 Alpha Tibia Nailing System

The T2 Alpha Tibia Nailing System is substantially equivalent to the previously cleared T2 Alpha Tibia Nailing System (K191271) and Titan Tibial Nail (K003018).

IMN Screws System

The IMN Screws System is substantially equivalent to the previously cleared IMN Screws System (K191271), Titan Tibial Nail (K003018), and Synthes Tibial Nail System Ex (K040762).